

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of : Adolf, G. et al) Art Unit: 1642
Serial No. : 10/645,215) Examiner: Huff, Sheela J.
Confirmation No. : 8054
Filed : August 21, 2003
Docket No. : 1/1383
For : COMPOSITIONS AND METHODS FOR TREATING
CANCER USING CYTOTOXIC CD44 ANTIBODY
IMMUNOCONJUGATES AND CHEMOTHERAPEUTIC
AGENTS

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**STATEMENT BY ATTORNEY
REGARDING DEPOSITED BIOLOGICAL MATERIAL**

Sir:

I, Susan K. Pocchiari, declare and state that:

1. I am an attorney of record in the captioned application in which I represent the inventors and Boehringer Ingelheim International (Int.) GmbH, present assignee of the application;
2. On June 7, 1994 a deposit was accepted with the DSMZ-Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH (DSMZ), in compliance with the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure on behalf of Boehringer Ingelheim Int. GmbH a hybridoma cell line identified as VFF-18 which was assigned Accession number DSM ACC2174;
3. For the hybridoma cell line referred to in paragraph 2, the deposited material is the same material identified in the above-identified application as filed;
4. I hereby assure the United States Patent and Trademark Office and the public that:
 - (a) all restrictions on the availability to the public of the culture referred to in

paragraph 2 will be irrevocably removed upon issuance of a United States Patent of which such culture is the subject; (b) each culture will be maintained for a period of at least five years after the most recent request for the furnishing of a sample of the deposited culture was received by the DSMZ and, in any case for a period of at least 30 years after the date of deposit; (c) should the deposit become non-viable it will be replaced by the Applicants; and (d) access to the culture will be available to the Commissioner during the pendency of the patent application or to one determined by the Commissioner to be entitled to such culture under 37 C.F.R. §1.14 and 35 U.S.C. §122;

5. Attached is a copy of the deposit certificates, including deposit form and viability statement, with the DSMZ for Deposit VFF-18, Accession number DSM ACC2174 that certifies that the deposit conforms to the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure.

I hereby declare further that all statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true and further I make these statements with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: January 18, 2005

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45,016

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22/03/2002 15:18 +49-7351-54-2172

BI PHARMA KG

S. 01/02

BUDAPEST TREATY ON THE INTERNATIONAL
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS
FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

Boehringer Ingelheim Int. GmbH

Postfach 200
55216 Ingelheim am Rhein

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT
issued pursuant to Rule 7.1 by the
INTERNATIONAL DEPOSITORY AUTHORITY
identified at the bottom of this page

I. IDENTIFICATION OF THE MICROORGANISM	
Identification reference given by the DEPOSITOR: VFF-18	Accession number given by the INTERNATIONAL DEPOSITORY AUTHORITY: DSM ACC2174
II. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION	
<p>The microorganism identified under I. above was accompanied by:</p> <p><input type="checkbox"/> a scientific description <input type="checkbox"/> a proposed taxonomic designation</p> <p>(Mark with a cross where applicable).</p>	
III. RECEIPT AND ACCEPTANCE	
<p>This International Depository Authority accepts the microorganism identified under I. above, which was received by it on 1994-06-07 (Date of the original deposit)¹.</p>	
IV. RECEIPT OF REQUEST FOR CONVERSION	
<p>The microorganism identified under I. above was received by this International Depository Authority on (date of original deposit) and a request to convert the original deposit to a deposit under the Budapest Treaty was received by it on (date of receipt of request for conversion).</p>	
V. INTERNATIONAL DEPOSITORY AUTHORITY	
Name: DSM-DEUTSCHE SAMMLUNG VON MIKROORGANISMEN UND ZELLKULTUREN GmbH Address: Münchener Weg 1b D-38114 Braunschweig	Signature(s) of person(s) having the power to represent the International Depository Authority or of authorized official(s): Date: 1994-06-17

¹ Where Rule 6.4 (d) applies, such date is the date on which the status of international depository authority was acquired.

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BI PHARMA KG

S. 02/02

BUDAPEST TREATY ON THE INTERNATIONAL
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS
FOR THE PURPOSES OF PATENT PROCEDURE

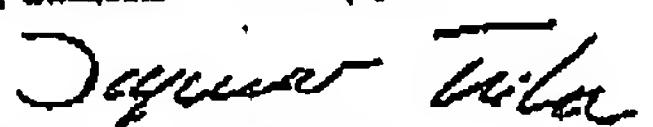
INTERNATIONAL FORM

Boehringer Ingelheim Int. GmbH

Postfach 200
55216 Ingelheim am Rhein

VIABILITY STATEMENT

Issued pursuant to Rule 10.3 by the
INTERNATIONAL DEPOSITORY AUTHORITY
Identified at the bottom of this page

I. DEPOSITOR		II. IDENTIFICATION OF THE MICROORGANISM
Name: Boehringer Ingelheim Int. GmbH Address: Postfach 200 55216 Ingelheim am Rhein		Accession number given by the INTERNATIONAL DEPOSITORY AUTHORITY: DSM ACC2174 Date of the deposit or the transfer ¹ : 1994-06-07
III. VIABILITY STATEMENT		
The viability of the microorganism identified under II above was tested on 1994-06-07 ² . On that date, the said microorganism was: <input checked="" type="checkbox"/> ³ viable <input type="checkbox"/> ³ no longer viable		
IV. CONDITIONS UNDER WHICH THE VIABILITY TEST HAS BEEN PERFORMED⁴		
V. INTERNATIONAL DEPOSITORY AUTHORITY		
Name: DSM-DEUTSCHE SAMMLUNG VON MIKROORGANISMEN UND ZELLKULTUREN GmbH Address: Maecholder Weg 1b D-38124 Braunschweig		Signature(s) of person(s) having the power to represent the International Depository Authority or of authorized official(s):  Date: 1994-06-17

¹ Indicate the date of original deposit or, where a new deposit or a transfer has been made, the most recent relevant date (date of the new deposit or date of the transfer).

² In the cases referred to in Rule 10.2(a) (ii) and (iii), refer to the most recent viability test.

³ Mark with a cross the applicable box.

⁴ Fill in if the information has been requested and if the results of the test were negative.